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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,742	06/01/2005	Corrado Fogher	GRT/4161-12	1064
23117 7590 06/26/2009 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER WORLEY, CATHY KINGDON	
			ART UNIT 1638	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,742	<b>Applicant(s)</b> FOGHER, CORRADO	
	<b>Examiner</b> CATHY K. WORLEY	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/10/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The amendment filed April 10, 2009, has been entered.
2. Claims 13-20 have been newly added and new claims 13 and 14 are drawn to the elected invention.

Claims 1-20 are pending.

Claims 5-12 and 15-20 are withdrawn.

3. Claims 1-4, 13, and 14, as they relate to SEQ ID NO:36, are examined in the present office action.

### ***Restriction/Election***

4. The Applicant requests reconsideration of the restriction requirement (see page 8 of the response). The restriction requirement is proper and was MADE FINAL in the previous Office Action mailed on Dec. 10, 2008. The linking claims were not found to be allowable, therefore, the different inventions have not been rejoined. The Applicant is reminded to amend the claims to recite only the elected sequence of SEQ ID NO:36. The products claims were not found to be allowable, therefore, the process claims have not been rejoined.

The Applicant is reminded that when the examiner has required restriction between product and process claims, and where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn

process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Information Disclosure Statement***

5. The Information Disclosure Statement (IDS) filed on April 10, 2009, has been considered. The Examiner has initialed the International Search Reports.

***Specification***

6. The abstract of the disclosure remains objected to because the amended abstract is not sufficiently descriptive of the invention. The abstract should be between 50 and 150 words in length and it should specify that transgenic non-wheat plants expressing wheat glutenins and transglutaminase are utilized. New matter must be avoided, therefore the Applicant is advised to utilize language that is present in the originally filed specification. Correction is requested. See MPEP § 608.01(b).

7. The amended title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed. The new title should specify that transgenic non-wheat plants expressing wheat glutenins and transglutaminase are utilized.

***Objections and Rejections that are Withdrawn***

8. The objections to claims 1-4 are withdrawn.
9. The rejections of claims 1-4 under 35 USC 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the Applicant's amendments to the claims, and in light of the Applicant's clarification that the linking claim encompasses embodiments in which one, more than one, all, or none of the allergenic amino acid sequences may be eliminated in accordance with the independent claim (see page 10 of the response).
10. The rejection of claims 1-4 under 35 USC 103(a) is withdrawn in light of the Applicant's correct observation that the gliadin taught by Arentz-Hansen does not comprise SEQ ID NO:11.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-4, 13, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a flour derived from the seed of a plant expressing transglutaminase and one or more genes coding for wheat storage proteins that comprise SEQ ID NO:11 and are selected from the group consisting of 1Bx7, 1By9, 1Dx5, 1Dy10, 1Ax2, 1Bx17, 1Ax1, 1Dy12, and HMW2, wherein said one or more genes are optionally modified by mutagenesis to eliminate allergenic amino acid sequences for food allergies to gluten; including wherein the sequence to be modified is SEQ ID NO:36 (the sequence elected in response to the restriction requirement).

The Applicants describe only 5 proteins that comprise SEQ ID NO:11; Ax1, Ax2, Dx5, HMW2, and Bx7 (see Table 1 on page 19 of the specification). The other four proteins recited do not comprise SEQ ID NO:11 (see Table 1 on page 19 of the specification). None of these 5 proteins comprise the elected peptide of SEQ ID NO:36 (see Table 1 on page 19 of the specification).

The Applicants do not describe any proteins that comprise SEQ ID NO:11 and also comprise SEQ ID NO:36.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangtong, V. (Dissertation (2001) from Iowa State University) in view of Schuhmann, F. (US Patent No. 6,517,874, issued on Feb. 11, 2003, and published as US Pre-Grant Publication US 2002/0061344 on May 23, 2002), and further in view of Whitelam, G. C. (J. Sci. Food Agric. (1995) Vol. 68, pp. 1-9).

The claims are directed to a flour which is derived from the seed of a plant expressing transglutaminase and one or more genes coding for wheat storage proteins that comprise SEQ ID NO:11 and are selected from the group consisting of 1Bx7, 1By9, 1Dx5, 1Dy10, 1Ax2, 1Bx17, 1Ax1, 1Dy12, and HMW2. Because mutagenesis of the storage protein is optional, it is not a requirement.

Sangtong teaches transgenic corn expressing the wheat gluten 1Dx5 protein (see entire document). 1Dx5 comprises SEQ ID NO:11 as evidenced by the instant application (see Table 1 on page 19 of the instant specification). Sangtong teaches that bread-making quality of tritordeum was significantly improved by transforming it to express 1Ax1 and 1Dx5 from wheat (see second paragraph on page 11). Sangtong states that "we would like to make maize with novel flour property. The Glu-1Dx5 gene encoding for 1Dx5 HMW glutenin subunit that contributes elasticity to wheat dough was transformed into maize. ... We will study the effect of 1Dx5 HMW glutenin subunit on maize flour property." It is known in the art that some people are allergic to wheat products (known as Celiac's disease);



therefore, the corn flour made from the transgenic maize that is taught by Sangtong would have been less allergenic than wheat flour.

Sangtong does not teach seeds of plants expressing transglutaminase.

Schuhmann teaches the addition of transglutaminase to flours, especially flours with low wheat content, to improve their dough properties, including retention of gas in the dough to result in an increase in bread volume (see column 2). Schuhmann teaches that the transglutaminase enzyme may be produced recombinantly (see column 4, lines 4-5).

Whitelam teaches that enzymes that are useful for processing of plant material can be produced recombinantly in the plants themselves (see introduction and pages 6 - 7). Whitelam specifically uses amylase and phytase as examples of such enzymes. In both of these cases the enzymes have traditionally been added to the plant material, but the experiments showed that they were successful in producing amylase and phytase in transgenic plants such that no exogenous enzyme would be required for processing (see pages 6-7).

At the time the inventions were made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the transgenic maize taught by Sangtong to express transglutaminase. One would have been motivated to do so because Schuhmann teaches that transglutaminase improves dough properties and Whitelam teaches that growing an enzyme recombinantly in the plant itself is preferable over adding it to plant material exogenously.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638